

**UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
BEAUMONT DIVISION**

UNITED STATES OF AMERICA
ex rel. BROOK JACKSON,

Plaintiff,

- v -

VENTAVIA RESEARCH GROUP, LLC;
PFIZER INC.; ICON PLC,

Defendants.

CASE NO. 1:21-CV-00008-MJT

ORAL ARGUMENT REQUESTED

**ICON PLC'S MOTION TO DISMISS RELATOR'S SECOND AMENDED COMPLAINT
AND MEMORANDUM OF LAW IN SUPPORT**

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Defendant ICON plc (“ICON”) respectfully moves, pursuant to the Federal Rules of Civil Procedure 9(b) and 12(b)(6), to dismiss Count I of the operative complaint (the “Second Amended Complaint” or “SAC”) [Dkt. No. 118].¹ ICON joins and incorporates by reference Defendant Pfizer Inc.’s (“Pfizer”) Motion to Dismiss Relator’s Second Amended Complaint and Memorandum of Law in Support (“Pfizer’s Motion”) and Defendant Ventavia Research Group, LLC’s (“Ventavia”) Motion to Dismiss Relator’s Second Amended Complaint and Brief in Support (“Ventavia’s Motion”), Part I.²

PRELIMINARY STATEMENT

It remains unclear why ICON is a defendant in this ill-conceived False Claims Act litigation. ICON did not submit any claim for payment or otherwise seek or receive any payment from the United States related to vaccine trials. Nor did ICON employ Plaintiff-Relator Brook Jackson (“Relator”). Instead, *as the Second Amended Complaint itself alleges*, ICON performed its role providing outsourced monitoring and related services to Pfizer for its landmark COVID-19 vaccine clinical trials, identifying concerns and working with the relevant teams to address and ameliorate them as the study progressed.

These fatal pleading deficiencies were apparent, and this Court dismissed all claims against ICON in the First Amended Complaint [Dkt. No. 17] (“FAC”) with prejudice. Nonetheless, and despite being given a second chance to try to bolster her claims, Relator’s amendments have added

¹ Counts II, III, and IV of the SAC have already been dismissed with prejudice and were included in the SAC solely for the purpose of preserving those claims for appeal. *See* Stipulation Regarding Relator’s Second Amended Complaint [Dkt. No. 116] at 1. Counts V and VI of the Second Amended Complaint are against Defendant Ventavia only and do not involve ICON.

² ICON additionally incorporates by reference its Motion to Dismiss Relator’s Amended Complaint and Memorandum of Law in Support [Dkt. No. 51] (“FAC MTD Br.”) and its Reply Memorandum of Law in Further Support [Dkt. No. 69] (“FAC MTD Reply Br.”).

zero specific allegations tying ICON to her fraudulent inducement claim under the False Claims Act (“FCA”). There are scarcely **any** new mentions of ICON in the Second Amended Complaint, and to the extent Relator has added any allegations involving ICON, she does so only by generically and inappropriately lumping in ICON with the rest of the Defendants, without specifying any alleged misconduct by ICON itself. In doing so, she relies almost entirely on allegations that this Court has already found lacking in dismissing Relator’s prior claims with prejudice. Relator’s second bite at the apple thus still falls far short of pleading **any** viable claim against ICON. Relator’s few new allegations against ICON remain nothing more than an afterthought, coming nowhere close to stating a claim under the FCA. In fact, according to Relator’s own allegations, ICON was frequently kept in the dark and even lied to about the alleged misconduct Relator claims (without any factual basis) others supposedly engaged in. The Second Amended Complaint should be dismissed with prejudice again as to all Defendants, and in particular as to ICON, for the following reasons.

First, Relator’s allegations fail to meet the heightened pleading standards of Federal Rule of Civil Procedure 9(b) that all FCA claims—including those based on a theory of fraudulent inducement—must satisfy. The feeble allegations against Defendants Pfizer, Ventavia, and ICON (together, “Defendants”) are generalized, conclusory, or speculative, and cannot state a claim with the particularity required by Rule 9(b). This fatal flaw characterized Relator’s previous complaint and remains unchanged here.

Second, Relator fails to adequately allege her new theory of fraudulent inducement against ICON. Specifically, the SAC fails to adequately allege that ICON made—or caused another Defendant to make—any false claims, statements, or representations to fraudulently induce the

government to enter into a contract or issue payment. Indeed, it makes no such allegations at all against ICON.

Finally, Relator fails to adequately allege that Defendants and, in particular, ICON *knowingly* submitted a false statement to the government—another requirement of all FCA claims, including those based on a theory of fraudulent inducement. Not only does the SAC fail to allege that ICON had actual knowledge of the alleged violations of trial protocol, it alleges instead that this supposed falsity was actively hidden from ICON. As with the Rule 9(b) pleading standard, this was a fatal flaw in Relator’s previous complaint and identified in ICON’s previous briefing, but Relator made no effort to address it in her amendments.

For all these reasons, as well as the reasons stated in Pfizer’s Motion and Ventavia’s Motion, which ICON joins and incorporates by reference herein, and as discussed more fully below, the Court should dismiss Count I of the Second Amended Complaint with prejudice.

FACTUAL BACKGROUND³

At the onset of the COVID-19 pandemic, ICON,⁴ an Irish-headquartered clinical research organization, was engaged by Pfizer to implement its strategic plan and framework for monitoring its landmark clinical study for a COVID-19 vaccine. ICON helped monitor trials, recruit trial participants, organize clinical supply management services, and provide site training, document management, and informed consent support.⁵ The two Ventavia sites that employed Relator were among the 153 sites that ICON worked with in the United States, Europe, South Africa, and Latin

³ ICON refers the Court to the Factual Background section of Pfizer’s Motion (*see* Pfizer’s Mot. at 6–12) and states additional factual background relating to ICON specifically herein.

⁴ For purposes of this Rule 12(b)(6) motion only, “ICON” refers to ICON plc and/or its relevant subsidiaries. ICON reserves all rights and defenses with respect to the identity of the correct parties.

⁵ “ICON Supports Pfizer and BioNTech on the investigational COVID-19 vaccine trial,” ICON, Jan 4, 2021, <https://www.iconplc.com/news-events/press-releases/icon-pfizer-biontech/>.

America. ICON was paid for its work entirely by Pfizer and is not alleged to have ever requested or received payment from the United States government.

On February 22, 2022, Relator filed her First Amended Complaint alleging violations of the FCA under 31 U.S.C. §§ 3729(a)(1)(A) (the “presentment claim”) and 3729(a)(1)(B) (the “false statement claim”) against Defendants. [Dkt. No. 17]. On March 31, 2023, the Court granted Defendants’ Motions to Dismiss [Dkt. Nos. 37, 51, and 53] with prejudice (as to all but the retaliation claim against Ventavia). *United States ex rel. Jackson v. Ventavia Rsch. Grp., LLC*, 2023 WL 2744394, at *26 (E.D. Tex. Mar. 31, 2023) [Dkt. No. 96] (“Opinion”). On August 9, 2023, the Court permitted Relator to file an amended complaint to assert an FCA fraudulent inducement claim. *See* Opinion Granting Leave to File a Second Amended Complaint [Dkt. No. 108] at 2–3. On October 5, 2023, Relator filed her Second Amended Complaint, under 31 U.S.C. § 3730(b), the *qui tam* provision of the FCA.

Relator’s Second Amended Complaint alleges that Defendants fraudulently induced the U.S. government to issue an Emergency Use Authorization (“EUA”) for Pfizer’s COVID-19 vaccine, violating the FCA. (SAC ¶¶ 309, 347–57). Despite these outlandish claims, however, Relator’s allegations as to ICON are as sparse as they were previously. In the First Amended Complaint that this Court dismissed with prejudice, Relator made unsupported assertions that ICON “turned a blind eye to Ventavia’s misconduct,” failed to “follow up on missing information,” ignored “red flags” of protocol violations and false data, failed to “exclude ineligible participants from the trial data,” and neglected to follow up on and report adverse event information. (*See* FAC ¶¶ 6, 9, 187, 213). Those allegations, which were found by this Court to be insufficient to state a claim, are repeated here. (SAC ¶¶ 15, 18, 242). In one of the few additions to the SAC that explicitly names ICON, Relator boldly pronounces the existence of “demonstrated

reckless monitoring by ICON . . . of clinical trial sites,” without alleging a single further detail (*id.* ¶ 163); all other additions to the SAC involving ICON only generically assert claims against all Defendants, rather than ICON specifically. (*See, e.g., id.* ¶¶ 348–49, 354–57). However, as in Relator’s prior complaint, the SAC’s exhibits show ICON personnel providing guidance to and asking questions of Ventavia personnel as part of its oversight of the landmark study and its responsibility to ensure clinical trial protocol compliance and required information reporting. (*Id.* Exs. 16 and 19). Unchanged from Relator’s previously dismissed-with-prejudice Complaint, the SAC still repeatedly claims that ICON had “constructive notice” of Ventavia’s alleged misconduct, but does not support this conclusion other than by stating that ICON had access to information in “source documents,” without further explanation. (*Id.* ¶¶ 200, 221).

LEGAL STANDARD

On a Rule 12(b)(6) motion to dismiss, a court “accepts all well-pleaded facts as true,” but is not required to “accept as true conclusory allegations, factual inferences, or legal conclusions.” Opinion at *8 (citing *Sonnier v. State Farm Mut. Auto. Ins. Co.*, 509 F.3d 673, 675 (5th Cir. 2007) and *Gentilello v. Rege*, 627 F.3d 540, 544 (5th Cir. 2010));⁶ *see also* Pfizer’s Mot. at 12–13.

Additionally, the heightened pleading requirements of Rule 9(b) apply to FCA fraudulent inducement claims, as they do to all fraud claims.⁷ *See United States ex rel. Willard v. Humana Health Plan of Texas Inc.*, 336 F.3d 375, 384–85 (5th Cir. 2003) (dismissing FCA fraudulent inducement claim for failing to meet Rule 9(b) standard). Rule 9(b) provides that “a relator must

⁶ Unless noted otherwise, emphasis is added and internal citations and quotation marks are omitted.

⁷ The particularity demanded by Rule 9(b) is supplemental to the Supreme Court’s interpretation of “Rule 8(a) requiring enough facts [taken as true] to state a claim to relief that is plausible on its face.” *United States ex rel. Dekort v. Integrated Coast Guard Sys.*, 705 F. Supp. 2d 519, 530 (N.D. Tex. 2010). “A dismissal for failure to plead fraud with particularity under Rule 9(b) is treated as a dismissal for failure to state a claim under Rule 12(b)(6).” *Id.*

plead ‘with particularity’ the circumstances surrounding the alleged fraud.” Opinion at *8 (citing Fed. R. Civ. P. 9(b)). The circumstances that must be pled with particularity are “the time, place, and contents of the false representation[], as well as the identity of the person making the misrepresentation and what that person obtained thereby . . . otherwise referred to as the ‘who, what, when, where, and how’ of the alleged fraud.” *Willard*, 336 F.3d at 384.

ARGUMENT

I. THE SECOND AMENDED COMPLAINT FALLS FAR SHORT OF MEETING RULE 9(b)’S HEIGHTENED PLEADING STANDARD.

The SAC fails to comply with the heightened pleading standards of Rule 9(b), as it does not allege anything of substance against ICON. Relator continues to treat ICON as a bit player, and the small number of allegations of misconduct as to ICON specifically remain conclusory or speculative.⁸ Indeed, Relator fails to meet Rule 9(b)’s pleading standards as to any Defendant, relying on blanket allegations against “Defendants” generally without the required specifics as to how *each* (or any) Defendant fraudulently induced the government to enter into a contract with Pfizer (*see* SAC ¶¶ 347–57). *See In re Parkcentral Global Litigation*, 884 F. Supp.2d 464, 470–71 (N.D. Tex. 2012) (Rule 9(b) requires that the “‘who, what, when, where, and how’ of the fraud must be laid out . . . as to each defendant,” because “[i]t is impermissible to make general allegations that lump all defendants together; rather, the complaint must segregate the alleged wrongdoing of one from another”).

The requirements of Rule 9(b) apply to FCA fraudulent inducement claims, as they do all FCA claims. *See Willard*, 336 F.3d at 384–86; *see also United States v. Dental Health Programs*,

⁸ Relator’s prior Complaint similarly failed to comply with Rule 9(b). *See* FAC MTD Br. at 8–10; FAC MTD Reply Br. at 2–5. The Court did not reach Defendants’ arguments concerning Rule 9(b) in its Opinion dismissing the prior Complaint. Opinion at *23 n.22.

Inc., 2020 WL 3064712, at *5 (N.D. Tex. June 8, 2020) (“[T]o state a claim for fraudulent inducement . . . Relator must allege the circumstances of the fraud with particularity”). Rule 9(b) requires that a complaint allege “as to ***each individual defendant*** the nature of the fraud, some details, [and] a brief sketch of how the fraudulent scheme operated, when and where it occurred, and the participants.” *Hernandez v. CIBA-GEIGY Corp. USA*, 2000 WL 33187524, at *5 (S.D. Tex. Oct. 17, 2000) (quoting *Askanase v. Fatjo*, 148 F.R.D. 570, 574 (S.D. Tex. 1993)). Courts in the Fifth Circuit apply Rule 9(b) to FCA claims “with bite and without apology.” *United States ex rel. Porter v. Magnolia Health Plan, Inc.*, 810 Fed. Appx. 237, 240 (5th Cir. 2020).

Relator’s claims against ICON, based entirely on a handful of generic and conclusory allegations and unsupported speculation, do not even pass muster under the more liberal pleading standard of Rule 8(a)(2), let alone Rule 9(b)’s exacting requirements. While Relator repeats allegations from the dismissed-with-prejudice Complaint that ICON ignored red flags of trial protocol violations and false data and “turned a blind eye” to alleged fraud (*see, e.g.*, SAC ¶¶ 18, 217), she again offers no specific details of the alleged red flags or falsified data—the necessary “who, what, when, where, and how” (*Willard*, 336 F.3d at 384)—as detailed in ICON’s prior motion to dismiss briefing. *See* FAC MTD Br. at 8–10; FAC MTD Reply Br. at 2–5. And, as was also the case with the prior Complaint, the SAC’s supporting exhibits demonstrate that ICON did not ignore issues with the clinical trial but actively followed up and worked with Ventavia personnel to correct them. (*See* SAC Exs. 16, 19).

The SAC does nothing to remedy these pleading deficiencies. In fact, it does not reference ICON at all in the twenty new paragraphs alleging fraudulent inducement. (SAC ¶¶ 3, 9, 139, 306–11, 347–57). The SAC’s only revision that bothers to mention ICON declares “demonstrated reckless monitoring by ICON,” (*id.* ¶ 163), but, as discussed above (*supra* at 4–5), this alleged

recklessness is not actually “demonstrated” at all anywhere in the SAC, much less so with the requisite particularity. Otherwise, the SAC merely adds conclusory allegations against “Defendants” as a whole, without explaining the involvement of *each* defendant or the details of *each* Defendant’s purported conduct. (*See, e.g.*, SAC ¶¶ 348–54).

Even Relator’s generic allegations as to how exactly “Defendants” induced the government into fraudulently entering a contract—her single remaining FCA theory—are particularly superficial, falling far short of the Rule 9(b) standard recognized by courts in this Circuit. *See, e.g., United States ex rel. Richardson-Eagle, Inc. v. Marsh & McLennan Cos.*, 2005 WL 3591014, at *7 n.18 (S.D. Tex. Dec. 30, 2005) (dismissing fraudulent inducement claim under Rule 9(b) where complaint “does not allege who was involved in the contract negotiations, or where and when the negotiations took place” and “[t]here are no facts alleged as to what was said before, during or after the contract negotiations”); *Willard*, 336 F.3d at 385 (dismissing fraudulent inducement claim under Rule 9(b) where complaint “does not allege who was involved in the negotiations, or where or when the negotiations took place, or . . . what was said before, during or after the contract negotiations”).

II. THE SECOND AMENDED COMPLAINT FAILS TO ALLEGE FACTS SUPPORTING A FRAUDULENT INDUCEMENT CLAIM AGAINST ICON.

As is discussed in further detail in Pfizer’s Motion, Relator’s Second Amended Complaint is bereft of any facts to sufficiently allege that any Defendant made any false claims or representations (or caused another Defendant to do so) to fraudulently induce the government to enter into a contract or issue payment. *See* Pfizer’s Mot. at Part I. This claim fails against ICON for this additional independent reason.

As this Court explained, fraudulent inducement under the FCA may arise “when the contract under which payment is made was procured by fraud. . . . [A]lthough the Defendants’ ‘subsequent claims for payment made under the contract were not literally false, [because] they derived from the original fraudulent misrepresentation, they, too, became actionable false claims.’” Opinion at *17 (quoting *United States ex rel. Longhi v. United States*, 575 F.3d 458, 467–68 (5th Cir. 2009)). Relator must allege that each Defendant “(1) had no intention to perform according to the terms of the contract, and (2) obtained payments under the contract that it was not legitimately entitled to.” Opinion at 17 (quoting *United States ex rel. Laird v. Lockheed Martin Eng’g & Sci. Servs. Co.*, 491 F.3d 254, 259 (5th Cir. 2007)).

Relator does not and cannot allege that ICON procured a government contract⁹ through fraudulent statements. Relator’s accusations merely repeat those from her prior dismissed-with-prejudice Complaint, now repackaged under a fraudulent inducement theory in which ICON is barely mentioned. *See Part I supra*. Relator is required to plead that ICON made a representation to the government that “amount[s] to an expression of fact which admits of being adjudged true or false in a way that [] admits of empirical verification.” *Dekort*, 705 F. Supp. 2d at 536; *see also United States ex rel. Wilson v. Kellog, Brown & Root*, 525 F.3d 370, 377 (4th Cir. 2008) (dismissing FCA claims under a fraudulent inducement theory where the “representations at issue . . . do not include objective falsehoods” but rather “involve several general and relatively vague maintenance provisions”); *United States ex rel. DRC, Inc. v. Custer Battles, LLC*, 472 F. Supp. 2d

⁹ As an initial matter, the supposed “contract” that Relator identifies—the EUA approval received by Pfizer from the FDA—is not a contract and, in any event, was issued *after* the United States government through the Department of Defense contracted with Pfizer to purchase the vaccine. *See* Opinion at 17; Pfizer’s Mot. at 8.

787, 797 (E.D. Va. 2007) (“It is well-established that the FCA requires proof of an objective falsehood.”).

Nothing in the SAC comes anywhere near meeting this requirement. At most, Relator asserts non-specific (and, as explained *supra*, contradictory) allegations that ICON ignored or violated trial protocols *after* the contract with the government was entered into by Pfizer. This is insufficient. *See United States ex rel. Graves v. ITT Educational Services, Inc.*, 284 F. Supp. 2d 487, 503 (S.D. Tex. 2003) (FCA claims, under the theory of fraudulent inducement, “require[] more than the allegation that a defendant has accepted federal funds while in violation of certain funding requirements.”). Without any plausible allegations that ICON intended from the start to violate trial protocols when the contracts were entered into, these allegations cannot support a fraudulent inducement theory of FCA liability. *See Dekort*, 705 F. Supp. 2d at 536 (finding fraudulent inducement theory implausible where “the actions described by Relator occurred *after* the contract had been awarded” (emphasis in original)).¹⁰

The only “statement” by ICON that Relator identifies is the Form FDA-1572 that ICON certified and submitted (yet another allegation unchanged in the SAC). (SAC ¶¶ 172, 323). But Relator does not allege that there were any false statements made by ICON in the Form FDA-1572. Indeed, as the Court previously recognized—and as remains the case in the SAC—Relator does not allege any specifics about the representations made by ICON in the Form FDA-1572, attaching a blank example form to the SAC (*id.* Ex. 5) rather than the form that ICON actually submitted. *See* Opinion at *2 n.7.

¹⁰ The Fifth Circuit has declined to expand the fraudulent inducement theory beyond inducement of contracts to inducement of regulatory approval (*see* Pfizer’s Mot. at 14–15) and, in any event, alleged regulatory deficiencies do not even come close to asserting fraud.

Moreover, nowhere in the SAC does Relator even allege a connection between the Form FDA-1572 and Pfizer’s application for the EUA—the fictional “contract” Defendants allegedly fraudulently induced. Nor does Relator allege that this form was material to the government’s payment decision. (*See* FAC MTD Br. at 15–17; FAC MTD Reply Br. at 7–8). And nowhere does Relator allege that the Form FDA-1572 was required for Pfizer’s EUA application; it instead alleges that FDA clinical trial sponsors, like Pfizer, must collect these forms from contract investigators, like ICON, for “all clinical trials of new drugs,” regardless of whether an EUA is sought. (SAC ¶¶ 51–52, 56).

Because Relator fails to plausibly allege that ICON fraudulently induced the government to enter into a contract, this claim must be dismissed with prejudice.

III. THE SECOND AMENDED COMPLAINT FAILS TO ALLEGE THAT DEFENDANTS ACTED WITH REQUISITE KNOWLEDGE.

Relator’s fraudulent inducement claims against ICON additionally require dismissal because Relator has failed to adequately allege that ICON (or any other Defendant) made an alleged false statement with the requisite scienter. *See Dekort*, 705 F. Supp. 2d at 535–36 (“In order to prove a fraudulent inducement claim, a plaintiff must demonstrate that: (1) there was a false statement or fraudulent course of conduct; (2) made or carried out with the requisite scienter . . .”). As explained in ICON’s prior briefing, Relator’s pleading fails to adequately allege scienter. *See* FAC MTD Br. at 17–20; FAC MTD Reply Br. at 8–10.¹¹ Like the other deficiencies in Relator’s previous Complaint, this fatal issue remains unchanged in the SAC.

¹¹ The Court did not reach the question of scienter in its Opinion dismissing the prior Complaint. Opinion at *23 n.22.

A relator must adequately allege that a defendant “had (1) actual knowledge of falsity, (2) acted with deliberate ignorance of the truth or falsity of the information provided, or (3) acted with reckless disregard of the truth or falsity of the information provided” at the time defendants were alleged to have fraudulently induced the government contract. *Longhi*, 575 F.3d at 468.

Relator, however, repeatedly suggests that ICON could **not** have acted with knowledge, because the alleged violations of regulations and procedures were **hidden from** ICON. (*See, e.g.*, SAC ¶¶ 175, 182, 187, 191, 200, 206, 208, 213–14, 226, 231, 235, 269, 279, 282). Relator elsewhere in the SAC restates conclusory assertions that ICON had “constructive notice” or “constructive knowledge” of purported violations. (*See, e.g., id.* ¶¶ 200, 207, 216, 221). In order to allege constructive knowledge, however, Relator must show that ICON “buried [its] head in the sand” and “failed to make simple inquiries which would alert [it] that false claims [were] being submitted.” *United States ex rel. Longhi v. Lithium Power Techs., Inc.*, 513 F. Supp. 2d 866, 875–76 (S.D. Tex. 2007). But Relator does not allege any specifics about ICON’s purported constructive knowledge, including who at ICON was allegedly responsible for reviewing “source documents” or electronic diary entries for the more than 40,000 clinical participants and comparing them to documents provided by Ventavia. Additionally, the exhibits to the SAC refute any suggestion that ICON failed to make inquiries or that it “buried its head in the sand.” *See supra* Part I. To the contrary, the exhibits show ICON making specific inquiries to Ventavia regarding the trials it was conducting.

Importantly, and decisively for a *qui tam* case, even if Relator had adequately alleged that ICON had knowledge of any purported violations of trial procedures (and she does not), this does not establish that ICON had actual knowledge of any material falsity of **claims or statements made to the government**. *See United States ex rel. Steury v. Cardinal Health, Inc.*, 2011 WL 13266915,

at *5 (S.D. Tex. Aug. 29, 2011), *report and recommendation adopted*, 2011 WL 13266916 (S.D. Tex. Sept. 27, 2011) (“[B]ecause the FCA is not a general ‘enforcement device’ for federal contracts, merely selling defective goods to the government is not enough to create liability . . . Instead, a plaintiff must show that a contractor actually made a false statement to secure payment for the goods.”).

Ultimately, even assuming that Relator’s allegations are true for purposes of evaluating this motion, the most the SAC asserts is that Defendants made errors or mistakes in their oversight of the clinical trial. But this is far from alleging a knowing violation. Under the FCA, while “a lie is actionable” a mere “error” is not. *United States, ex rel. Johnson v. Kaner Med. Grp., P.A.*, 641 F. App’x 391, 394 (5th Cir. 2016). “Given this definition of ‘knowingly,’ courts have found that the mismanagement – alone – of programs that receive federal dollars is not enough to create FCA liability.” *Id.* (quoting *United States ex rel. Farmer v. City of Hous.*, 523 F.3d 333, 339 (5th Cir. 2008)). “Innocent mistakes, mere negligence, or even gross negligence (without more) are not actionable under the False Claims Act.” *United States ex rel. Guzder v. MKM Engineers Inc.*, 2009 WL 10697658, at *5 (S.D. Tex. May 1, 2009), *report and recommendation adopted sub nom. United States v. MKM Engineers Inc.*, 2009 WL 10697687 (S.D. Tex. June 25, 2009).

Because Relator fails to adequately allege that Defendants acted with scienter, her FCA claim must be dismissed.

CONCLUSION

For the foregoing reasons, in addition to those set forth in Pfizer’s and Ventavia’s Motions, ICON respectfully requests that the Court dismiss the claims asserted against ICON in their entirety with prejudice. ICON also requests oral argument on this motion.

Date: October 20, 2023

Respectfully Submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the foregoing document was served upon all counsel of record on October 20, 2023, pursuant to the Court's ECF filing system and the Federal Rules of Civil Procedure.

/s/ Scott L. Davis
Scott L. Davis